

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:
Irene Quenville et al.	: Confirmation No.: 2124
	:
Serial No. : 10/725,233	: Examiner: Gregory R. Delcotto
Filed: December 1, 2003	: Art Unit: 1796
	:
Title: STABILITY ENHANCEMENT OF SOLUTIONS CONTAINING ANTIMICROBIAL AGENTS	: Attorney Docket No.: P03346
	:

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Commissioner for Patents
P.O. Box 1450
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DECLARATION OF DAVID J. HEILER UNDER 37 C.F.R. § 1.132

I, David J. Heiler, one of the listed inventors of the invention disclosed and claimed in patent application, serial number 10/725,233, filed December 1, 2003 declare as follows:

1. I am presently employed as a Research Scientist at Bausch & Lomb ("B&L"), and I have been employed at B&L since 1988. One of my primary responsibilities during this time, and to this day, includes the development of next generation lens care solutions.
2. In early 2003, I was involved in the development of "ReNu-2", a next generation lens care solution that contained poly(hexamethylene biguanide) and a mixture of a poloxamine and poloxamer surfactants. See, test solution I reported in Table 1, page 14 of the application.
3. Attached to this Declaration is a redacted version of a Record of Invention submitted to the Patent Legal Department by Irene Quenville, a coinventor of the subject matter claimed. The statements made in the Record of Invention are incorporated into this Declaration with the following clarifications: Exhibits 1, 2 and 3 correspond to Figures 1, 3 and 2 of the application, respectively.
4. I reviewed the raw biocidal log reduction data that was used in-part to prepare the graphical representations of that data as shown in Figures 1, 2 and 3 of the application. I have also reviewed Tables 1 thru 11 (attached to this Declaration), which were prepared by Joseph Barrera, a B&L patent attorney, from the biocidal log reduction data. The data

listed in Tables 1 thru 11 is an accurate representation of the raw biocidal log reduction data.

5. For reference, Tables 1, 4 and 8 include the raw and mean initial time data for test solution 1 in PET and HDPE. As indicated by the biocidal stability data, test solution 1 remains biocidal active in the PET container but not in the HDPE container. At three months, there is statistically no change in the biocidal efficacy of test solution 1 in the PET container. In contrast, there is greater than a 50% reduction in biocidal activity of test solution 1 in HDPE. Similar results are indicated with the biocidal stability data at six months for test solution 1 in PET and HDPE containers. There is about a loss of 30% activity of the solution in the PET container at six months. In contrast, test solution 1 is virtually inactive, that is, shows no statistical biocidal activity in the HDPE container at six months.

All statements made by the declarant, which are based on personal knowledge, are true or believed to be true. Furthermore, these statements are made with the knowledge that willful false statements are punishable by fine or imprisonment or both and can jeopardize the validity of any US patent that may issue from the above-identified application.


David J. Heiler

Date: 24-Jan-2018